K111758
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510(k) SUMMARY

FEB 14 2012

1. NAME/ADDRESS OF SUBMITTER

DOG Microsystems Inc.
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Granby,Quebec, Canada
J2G 2V2

2. CONTACT PERSON

Emmanuel Montini
BCF Certification Inc.
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3. Date Summary Prepared: Friday, January-27-12

4. DEVICE NAME

CADENS™ Colon

5. COMMON NAME

Accessory to Computed Tomography X-ray System

6. REGULATION NAME

Picture Archiving and Communications System

7. REGULATION NUMBER

21 CFR 892.2050 Class II, PRODUCT CODE: 90-LLZ

8. PREDICATE DEVICES

- *Siemens* Syngo Colonography software package *(K030982)*
- *VITAL Images Vitrea (K043333)*
- *Viatronix V3D Colon, rev 1.3 (K040126)*

9. DEVICE DESCRIPTION

Similar to the *Siemens* Syngo Colonography software package, VIATRONIX V3D Colon *and VITAL Images CT Colonography*, the CADENS™ Colon is indicated for use and designed for the support of authorized physicians in reviewing relevant CT scanner images of Colorectal Cancer patients. The CADENS™ Colon is similar in intended use to the above *Siemens and VITAL Images* solutions combined with the electronic cleansing intended use of the Viatronix medical device.

10. INTENDED USE

CADENS™ Colon is a self-contained image analysis software package for evaluating CT volume datasets. Combining enhanced commercially available digital image processing tools with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-luminal view), the wall and the outside

(extra-luminal view) of the colon. *It provides functionality for display, measurement and electronic cleansing to assure complete visualization of the colon from rectum to cecum and vice versa for both prone and supine views.* With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue, with respect to their size, dimensions, shape and position.

It is to be used only by trained and instructed health care professionals.

8. General Safety and Efficacy examination

CADENS™ Colon has been tested and verified in various phases, including design review, internal verification and validation. The design was verified throughout a design process; internal validations included bench testing and practical testing in a simulated clinical environment. Hazard analysis was carried out during a Risk Management Plan, and appropriate measures were implemented and their effectiveness was verified.

Predicate Device Comparison and Conclusion

CADENS™ Colon has similar intended uses as the predicate devices and has very similar technological characteristics. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. Thus, CADENS™ Colon is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DOG Microsystems Inc.
% Mr. Emmanuel Montini
Consultant
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1100 Rene-Levesque West, 25th Floor
H3B 5C9 MONTREAL (QUEBEC)
CANADA

FEB 14 2012

Re: K111758
Trade/Device Name: CADENS™ Colon
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 31, 2012
Received: February 1, 2012

Dear Mr. Montini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K111758 **Device Name: CADENS™ Colon**

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Device Name: CADENS™ Colon

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Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111758

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation & Safety (OIVD)